

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000N-1409]



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**Medical Devices; Reclassification of the Iontophoresis Device**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of intent.

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**SUMMARY:** The Food and Drug Administration (FDA) announces an opportunity to submit information and comments concerning FDA's intent to initiate a proceeding to reclassify those iontophoresis devices currently in class III (premarket approval) into class II (special controls). An iontophoresis device is a device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for diagnostic or other uses. Elsewhere in this issue of the **Federal Register**, FDA is withdrawing the proposed rule the agency issued in the **Federal Register** of August 22, 2000 (65 FR 50949) (the August 2000 proposed rule).

**DATES:** Submit written or electronic comments by *[insert date 90 days after date of publication in the **Federal Register**]*.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827-2974.

**SUPPLEMENTARY INFORMATION:****I. Background**

In the **Federal Register** of November 23, 1983 (48 FR 53032), FDA issued a final rule classifying the iontophoresis device into class II (performance standards before the Safe Medical Devices Act of 1990 and now special controls) and class III (premarket approval), depending on its intended use. An iontophoresis device is a device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for diagnostic or other uses. If the iontophoresis device is intended for use in the diagnosis of cystic fibrosis or another intended use and the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, the device is categorized as class II. An iontophoresis device that is intended to introduce ions of soluble salts or other drugs into the body for other purposes is categorized as class III.

In the **Federal Register** of August 22, 2000, FDA proposed to amend the physical medicine devices regulations to remove the class III (premarket approval) iontophoresis device identification. FDA proposed this action because it believed that there were no preamendments iontophoresis devices marketed for uses other than those described in the class II identification. FDA expected that manufacturers of those devices currently in class III would be able to relabel their devices to meet the class II identification.

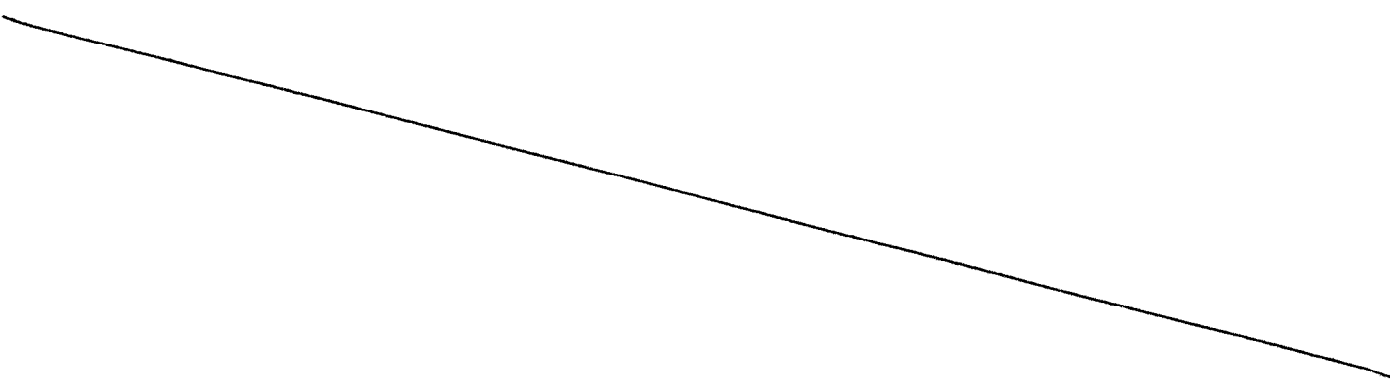
In response to the August 2000 proposed rule, FDA received seven comments. Several comments disagreed with FDA's assertion that no class III preamendments iontophoresis devices existed. Two comments were confused as to whether the requirement that a drug used with an iontophoresis device bear adequate directions for use with that specific device applies to the

diagnosis of cystic fibrosis or applies only to other uses. Two comments asserted that the assumption that there are differences in iontophoresis devices that would warrant linking a particular device to a particular drug is in error, and suggested that FDA should consider reclassification of iontophoresis devices into either class I or class II as drug delivery systems comparable to syringes and pumps. In contrast, another comment rejected what it perceived as the implication that all iontophoresis drug delivery systems were the same and that any iontophoresis device could be relabeled to reference any drug approved for iontophoretic administration, whether or not the drug had actually been tested for use with that particular device.

FDA is issuing this document to provide interested persons with an opportunity to submit any new information concerning the safety and effectiveness of the iontophoresis device. After FDA reviews any information that the agency receives in response to this document, FDA will decide whether the agency should go forward with the reclassification of those iontophoresis devices currently in class III and whether a panel meeting is necessary before taking any action.

## **II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except individuals may submit one paper copy. Comments are



to be identified with the docket number found in brackets in the heading of this document. Any received information may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 10/25/04

October 25, 2004.

Linda S. Kahan

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